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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland
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Gentlemen:

I am writing on behalf of the Canadian Trucking Alliance (CTA) in response to the re-opening of the comment period on Docket No. 2002N-0278, "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" as reported in the Federal Register on April 14, 2004. These comments are being submitted in conformance with the deadline set in a subsequent Federal Register notice of May 18, 2004.

By way of background, CTA is a federation of Canada's regional and provincial trucking associations formed to represent the views of the industry on national and international policy issues. CTA member associations include:

- Atlantic Provinces Trucking Association
- Quebec Trucking Association
- Ontario Trucking Association
- Manitoba Trucking Association
- Saskatchewan Trucking Association
- Alberta Motor Transport Association
- British Columbia Trucking Association

The associations comprising the CTA federation collectively represent some 4,000 companies across Canada. The Canadian trucking industry as a whole generates over $50 billion per year in freight revenue, and provides employment for some 400,000 people. Cross-border operations between the United States and Canada are significant, with over 13 million truck trips across the border each year carrying almost 70 per cent of the trade between the two countries. Further information on CTA and the Canadian trucking industry can be found at www.cantruck.com.

Before responding to the specific questions which appear in the Federal Register, CTA would like to make some general observations regarding the prior notice provisions of the *Bioterrorism Act.*

- To date it would appear that problems *at the border* have been minimal, probably owing to the fact that we have not yet moved to full enforcement. However, this masks the tremendous amount of time, effort and expense carriers have had to go to comply with the prior notice regulation. These costs include time spent with food shippers making suitable arrangements to provide prior notice, time spent verifying that prior notice information has been received and submitted by brokers, and in the case of carriers who are submitting information on behalf of clients, the direct time and expense of submitting prior notice.

?? As a general rule, CTA believes that there should be a harmonized approach for CBP and FDA for processing food shipments. Some progress has been made in bridging the gap between the two agencies since the initial proposals were published, but CTA feels more can be done, as outlined in our responses to the detailed questions below.

?? CTA is of the view that the requirement to submit FDA prior notice on Canada-to-Canada shipments in transit through the US is excessive. There is a well established bilateral approach already in place whereby trailers are sealed and moved in-transit under customs control. It is not clear what security benefit the US derives from receiving prior notice on these domestic Canadian shipments.

The in-transit requirements are particularly troublesome for carriers operating into certain Canadian communities where the only reasonable land access is via the United States. For example, Canadian carriers supplying grocery stores on Campobello Island have to ensure that prior notice is submitted on literally hundreds of food products on a single truck even though the goods have a Canadian origin and destination, and move through the US under CBP control. In other situations the most direct route between two Canadian points is through the United States. CTA has already been advised by one carrier that it will no longer transit US territory – and instead take a much longer route domestically – because of the FDA prior notice requirements.

CTA is mindful of the fact that CBP, under the *Trade Act*, is also expected to require prior notice for in-transit shipments. We would urge FDA to re-visit its requirements so that an additional and largely redundant layer of requirements is not imposed.

?? CTA would like to again note that the prior notice time frames - even if they are harmonized to CBP's - are deceiving, since the clock only starts ticking once FDA receives the information it needs from the filer (generally a broker). Furthermore, PN confirmation numbers are sent back to the filer and not to the carrier who will move the goods across the border. The net result is a significant waste of time and money as carriers chase down PN numbers from either the broker or the shipper before they dispatch a load to the border. Finding a means to submit the confirmation number directly to the carrier would reduce these costs and the administrative burden that goes along with it.

?? One of the biggest complaints one hears about FDA from carriers is hours of operation at the border. Clearly this impacts on carrier operations and is causing problems for cross border food shippers, especially those shipping perishable commodities. This is also placing a strain on drivers, who can be held up for significant periods of time, especially on weekends, if there is no FDA presence. CTA would urge FDA to examine current staffing practices with a view to ensuring FDA services are available at the border to those who require them, when they are required, including evenings and weekends.

?? It would appear that problems are still being encountered by virtue of the fact that not all brokers interact with FDA in a completely electronic environment. The Automated Broker Interchange (ABI) allows for the fully electronic transmission of CBP and FDA data, but so-called “dual mode” brokers must also submit information to FDA in paper form. If the customs entry and FDA information is complete and accurate, the driver will be given a message to proceed from the officer in the primary booth; but the same officer will not know if the driver must also submit paperwork to FDA at secondary. The result can be a driver leaving the customs compound and proceeding to the consignee without the necessary FDA approval. Dual mode brokers also force an extra stop at secondary, creating inefficiencies for food carriers and US importers at ports of entry, and forcing trucks to occupy valuable space in CBP secondary inspection commercial parking areas. To avoid problems like these FDA and CBP are encouraged to work in cooperation to ensure there is a mechanism to allow officers in the booth to know when a driver must report to FDA at secondary. It would also be prudent for FDA to encourage all brokers to participate in paperless electronic processing.

Turning now to the specific questions that appear in the Federal Register notice of April 14, 2004, CTA offers the following responses:

C-TPAT/FAST Questions

1. *Should food products subject to FDA's prior notice requirements be eligible for the full expedited processing and information transmission benefits allowed with C-TPAT and FAST? If so, how should this be accomplished?*

Yes. Importers, carriers and drivers who have been approved for C-TPAT and FAST have already been deemed to be "low risk" by CBP. Importers and carriers have had to demonstrate supply chain security controls, and drivers have been subjected to rigorous background screening. The federal governments of the United States and Canada have encouraged FAST participation on the grounds that it will mean expedited border crossings and reduced information requirements. A move by FDA to allow food to move through the FAST "stream" in the same manner as other products would demonstrate the commitment to harmonization that industry has long encouraged.

2. *If the timeframe for submitting prior notice for food arriving by land via road is reduced to 1 hour consistent with the timeframe in the advance electronic information rule, would a shorter timeframe be needed for members of FAST?*

Yes. The key premise behind the FAST program is that known, low-risk parties should receive expedited treatment at the border, freeing up enforcement resources to concentrate on parties of higher or unknown risk. That is exactly why the time frames CBP adopted are shorter for FAST than for other shipments. CTA believes FDA should adopt the half hour time frame for this reason; it would demonstrate a commitment to harmonize with CBP, and prevent a situation whereby FAST requirements vary depending on the type of commodity carried.

3. Should the security and verification processes in C-TPAT be modified in any way to handle food and animal feed shipments regulated by FDA? If so, how?

No. As noted above, in order to become C-TPAT approved, carriers and importers (including Canadian shippers acting as the US importer of record) must demonstrate that supply chain security controls are in place, and drivers are required to undergo rigorous background security checks. Layering a second set of requirements on top of those already in place would be of questionable value, and would require many parties who are already C-TPAT approved to undergo yet another qualifying process. This would completely defeat the purpose of efforts to harmonize FDA and CBP processes and requirements.

Flexible Alternative Questions

1. *If timeframes are reduced in FDA's prior notice rule, would other flexible alternatives for participants in FAST or for food imported by other agencies be needed?*

CTA's primary interest at this stage is seeing food products, regardless of who regulates them, brought under the same rules and requirements as other products moving through the FAST stream. This implies not only reduced time frames, but reduced information requirements and fewer inspections at the border.

2. *In considering flexible alternatives for food imported by other government agencies, what factors or criteria should FDA consider when examining alternatives? Should participation be voluntary? If so, should FDA consider inspection of companies in the supply chain from the manufacturer to those who may hold the product, including reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities as a condition of participation?*

As noted in point 1 above, CTA believes that all food products should be allowed to move through the FAST stream in the same manner as other products, and applicants should be judged on the same security criteria. C-TPAT should remain strictly voluntary. Under C-TPAT a process already exists to collect and validate security information from applicants (including Canadian food shippers acting as the US importer of record) so to subject these companies to additional inspections would be redundant and of questionable value from a security standpoint.

3. *In considering flexible alternatives for submission of prior notice, should FDA consider additional means of ensuring that all companies subject to the registration of food facilities interim final rule ((68 FR 58894, October 10, 2003 (21 CFR part 1, subpart H)), have an updated registration on file with FDA that has been verified?*

The existing registration process already provides FDA with detailed information on foreign facilities who ship food products into the United States. These facilities must also have an agent in the United States, and identify their agent to FDA. It is not clear what this additional requirement would accomplish.

4. Are there conditions of participation that FDA should consider, e.g., inspections of companies in the supply chain from the manufacturer to those who may hold the product, reviews of their security plans to determine what procedures are in place to prevent infiltration of their facilities?

FDA requires all foreign food shippers to register and appoint an agent in the United States. It requires extremely detailed prior notice information on all food imports, and runs this information through a sophisticated targeting tool. To also begin a process of examining the security plans and procedures of foreign food facilities would be tremendously expensive, call into question the validity of the prior notice and registration requirements already in place, and the efficacy of the targeting tools FDA employs.

5. Should the food product category be considered as a criteria or element of expedited prior notice processing or other flexible alternatives? If so, should certain foods be excluded from expedited prior notice processing? If so, what should be the basis for determining which foods should be excluded?

CTA believes that all food products should be eligible for expedited processing if the importer (including Canadian shippers acting as the US importer of record) and carrier are C-TPAT approved and the driver has obtained a FAST card.

6. If FDA adopts reduced timeframes in the prior notice final rule, should FDA phase in the shorter timeframes as CBP phases in the advance electronic information rule?

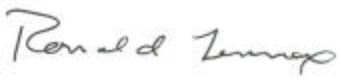
Yes. This would be a further step towards harmonization of FDA and CBP requirements.

7. Should FDA offer a prior notice submission training program for submitters and transmitters, including brokers, to ensure the accuracy of the data being submitted?

Accuracy of data is critical for carriers, because if there is a problem it is the truck and the driver who will be idled at the border. An FDA training program may be helpful in this regard.

CTA wishes to thank the FDA for the opportunity to comment on this matter, and would be pleased to respond to any questions you may have regarding this submission.

Sincerely,



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